

1824 South Robertson Blvd.  
Los Angeles, CA 90035-4317  
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www.Jarrow.com

### FAX NUMBERS

Orders 800/890-8955  
General 310/204-2520  
Administrative 310/204-5132

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)  
5100 Paint Branch Parkway  
College Park, Maryland 20740  
Reference phone #301-436-2373

July 23, 2004

AUG - 6 2004

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name and Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Statements:**

Vitamin D3 (cholecalciferol) is from purified fish liver oil and is free of Vitamin A. Fat-soluble Vitamin D3 is converted by the kidneys into the hormone calcitriol, the activated form of Vitamin D3 which affects a variety of target tissues including bone, intestine, muscle, brain, skin and immune systems cells. Calcitriol enhances calcium and phosphorous absorption and stimulates the synthesis of osteocalcin, an important structural protein in bone. Also, calcitriol is involved in proper cell differentiation (changing of cell function).

**(3) Name of the dietary ingredient(s) if not provided in the text of the statement:**

Vitamin D3 (cholecalciferol)

**(4) Name of the dietary supplement(s):**


Vitamin D3 — 40 IU, 100 softgels

**(5) The following disclaimer appears on the label in bold:**

These statements have not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of the nutrients.

Respectfully submitted,



Siddharth Shastri, M. Sc.  
Vice President, Product Development

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